



You are the Key to HPV Cancer Prevention

Understanding the Burden of HPV Disease,
the Importance of the HPV Vaccine Recommendation,
and Communicating about HPV Vaccination

Ken Cheyne, MD
Adolescent Medicine
Blank Children's Hospital

Disclosures

- ➡ I have no relevant financial relationships with the manufacturer(s) of any commercial products or services discussed in this continuing education activity.
- ➡ I do not intend to discuss unapproved/investigative use of commercial product(s)/device(s) in my presentation.

Objectives

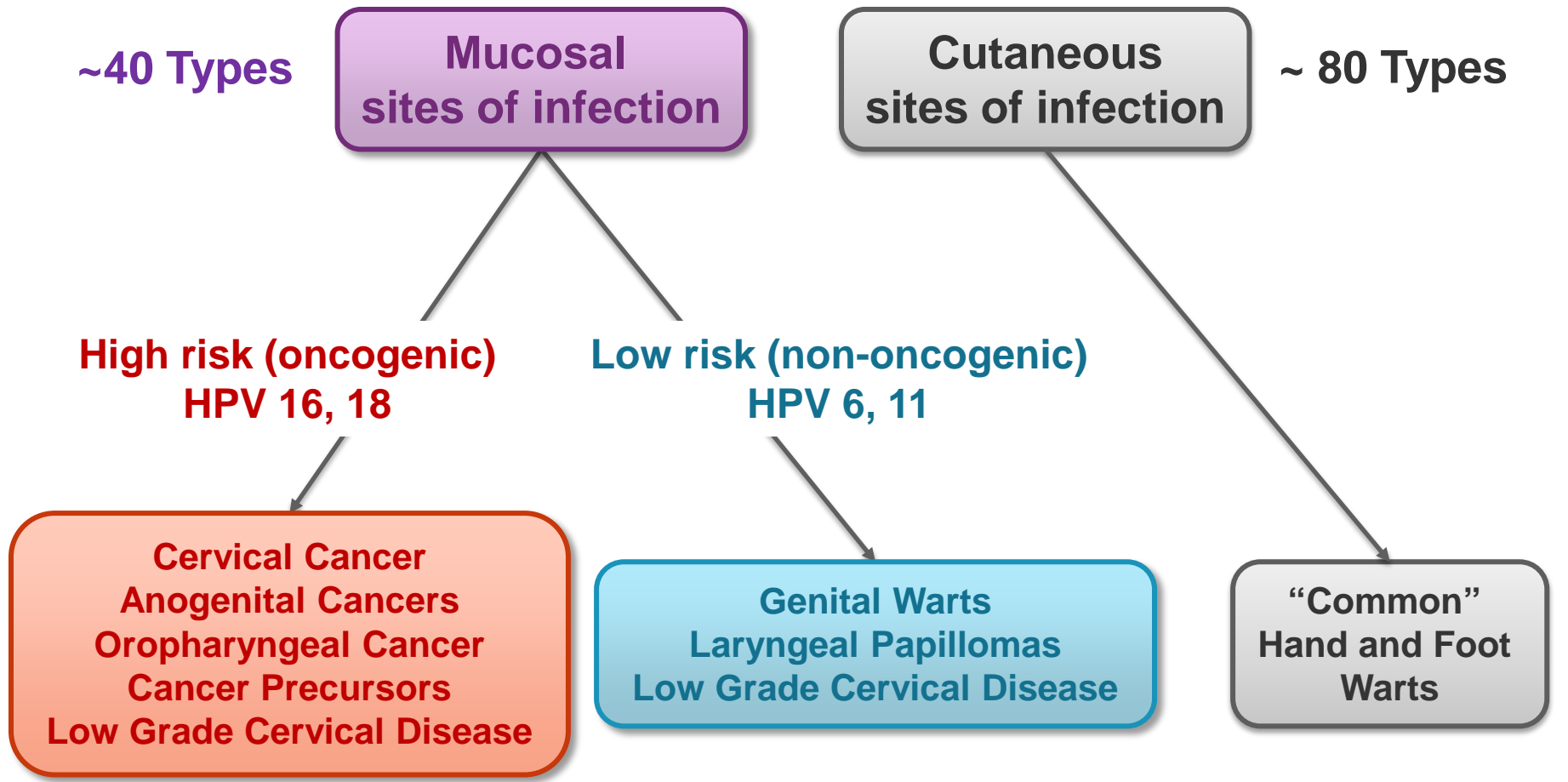
- 1.** Describe the burden of HPV infection and related disease.
- 2.** Provide information about HPV vaccination, including recommendations, safety, and impact.
- 3.** Share and employ best practices for HPV vaccine communication and strong recommendations.



Understanding the Burden

HPV INFECTION & DISEASE

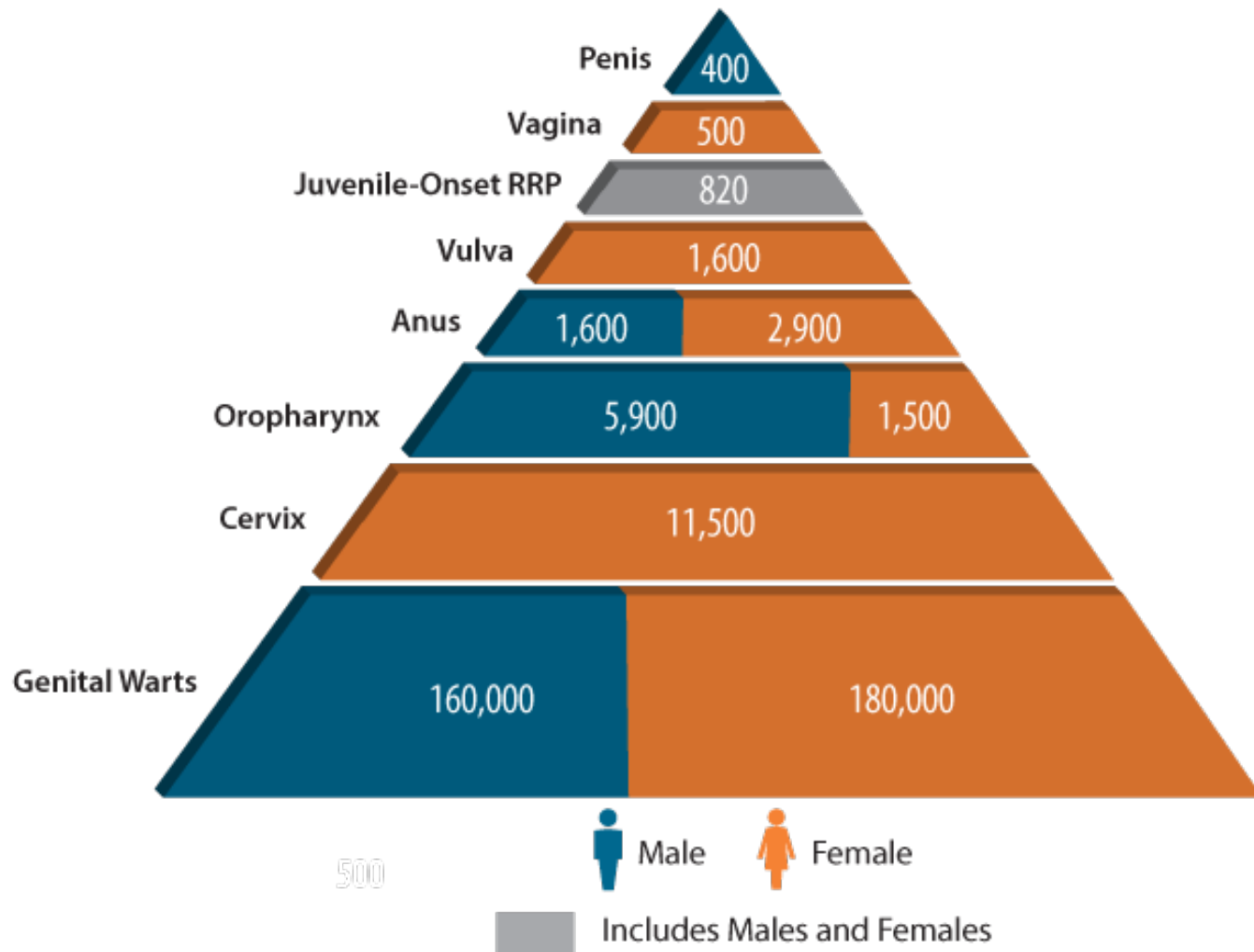
HPV Types Differ in their Disease Associations



HPV Infection

- ➡ **Most females and males will be infected with at least one type of HPV at some point in their lives**
 - ➡ Estimated 79 million Americans currently infected
 - ➡ 14 million new infections/year in the US
 - ➡ HPV infection is most common in people in their teens and early 20s
- ➡ **Most people will never know that they have been infected**

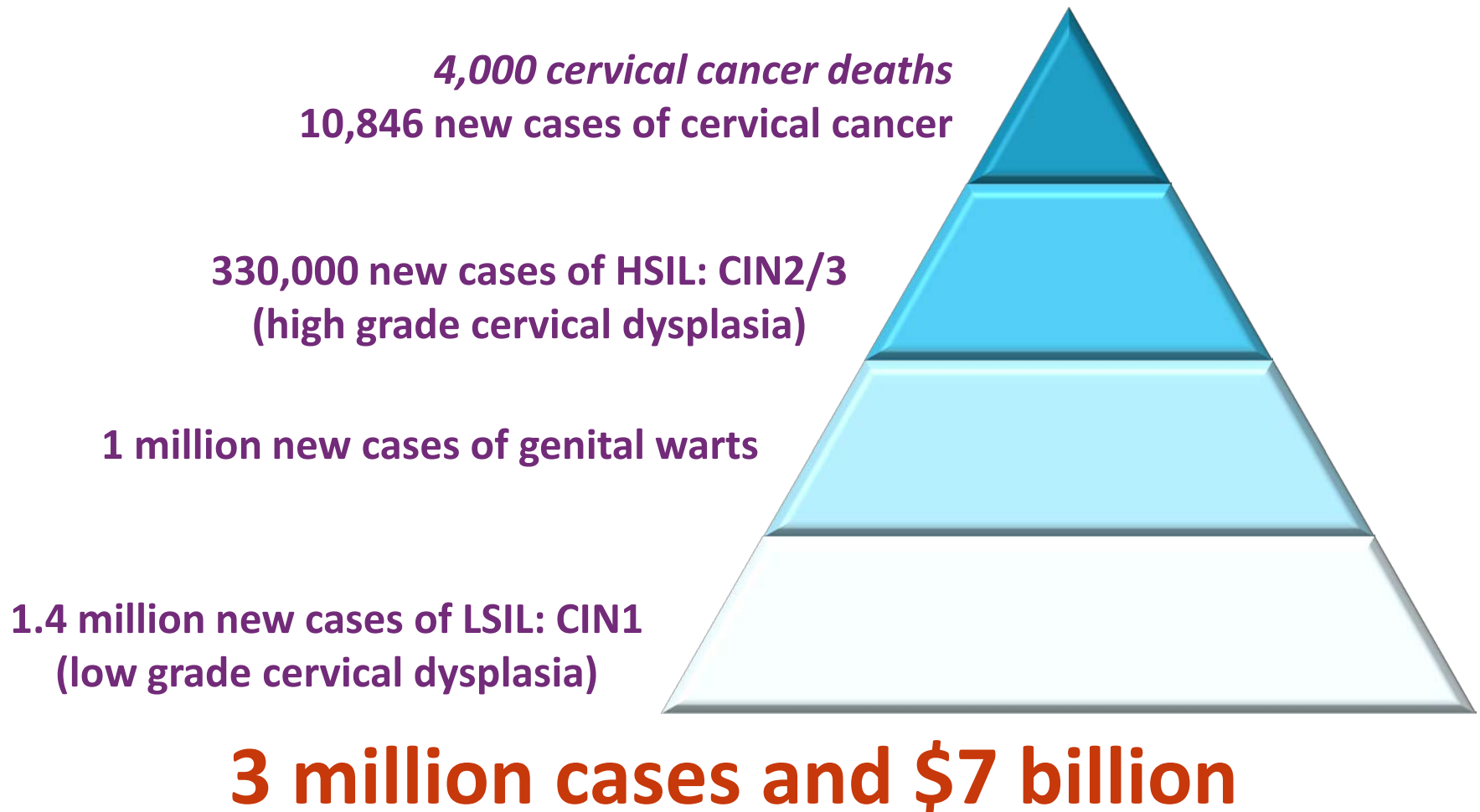
Numbers of Cancers and Genital Warts Attributed to HPV Infections, U.S.



Cervical Cancer

- ➡ **Cervical cancer is the most common HPV-associated cancer among women**
 - ➡ 500,000+ new cases and 275,000 attributable deaths world-wide in 2008
 - ➡ 11,000+ new cases and 4,000 attributable deaths in 2011 in the U.S.
- ➡ **37% cervical cancers occur in women who are between the ages of 20 and 44**
 - ➡ 13% (or nearly 1 in 8) between 20 and 34
 - ➡ 24% (or nearly 1 in 4) between 35 and 44

Without vaccination, annual burden of genital HPV in U.S. females:





Evidence-Based HPV Prevention

HPV VACCINE

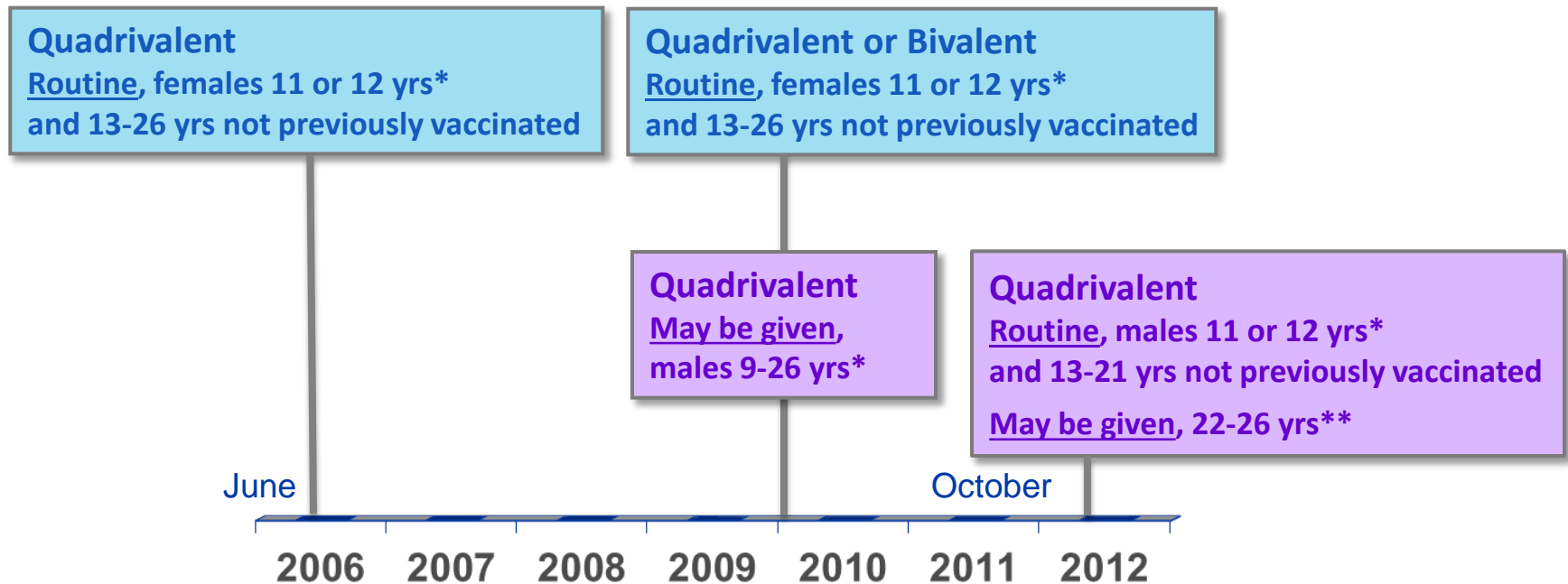


HPV Vaccine



Quadrivalent/HPV4 (Gardasil)	Name	Bivalent/HPV2 (Cervarix)
Merck	Manufacturer	GlaxoSmithKline
6, 11, 16, 18	Types	16, 18
Females: Anal, cervical, vaginal and vulvar precancer and cancer; Genital warts Males: Anal precancer and cancer; Genital warts	Indications	Females: Cervical precancer and cancer Males: Not approved for use in males
Hypersensitivity to yeast	Contraindications	Hypersensitivity to latex (latex only contained in pre-filled syringes, not single-dose vials)
3 dose series: 0, 2, 6 months	Schedule (IM)	3 dose series: 0, 1, 6 months

Evolution of recommendations for HPV vaccination in the United States



Quadrivalent (HPV 6,11,16,18) vaccine; Bivalent (HPV 16,18) vaccine

* Can be given starting at 9 years of age; ** For MSM and immunocompromised males, quadrivalent HPV vaccine through 26 years of age

ACIP Recommendation and AAP Guidelines for HPV Vaccine

- ➡ Routine HPV vaccination recommended for both males and females ages 11-12 years
- ➡ Also ages 13-21 years for males; 13-26 for females
- ➡ Vaccine can be given starting at age 9 years of age for both males and females; vaccine can be given ages 22-26 years for males

HPV Vaccination Schedule

- ACIP Recommended schedule is 0, 1-2*, 6 months
 - Following the recommended schedule is preferred
- Minimum intervals
 - 4 weeks between doses 1 and 2
 - 12 weeks between doses 2 and 3
 - ❖ 24 weeks between doses 1 and 3
- Administer IM

HPV Vaccine Is Safe, Effective, and Provides Lasting Protection

➡ HPV Vaccine is **SAFE**

- ➡ Safety studies findings for HPV vaccine similar to safety reviews of MCV4 and Tdap vaccines

➡ HPV Vaccine **WORKS**

- ➡ High grade cervical lesions decline in Australia (80% of school aged girls vaccinated)
- ➡ Prevalence of vaccine types declines by more than half in United States (33% of teens fully vaccinated)

➡ HPV Vaccine **LASTS**

- ➡ Studies suggest that vaccine protection is long-lasting; no evidence of waning immunity



HPV VACCINE SAFETY

HPV Vaccine Safety Monitoring

The Vaccine Adverse Event Reporting System (VAERS)

- An early warning public health system where people can report adverse health events following vaccination, that helps CDC and FDA detect possible new, unexpected, or increased trends in reported adverse events

The Vaccine Safety Datalink (VSD)

- Collaboration between CDC and several healthcare organizations which uses de-identified health records to monitor and evaluate adverse events following vaccination

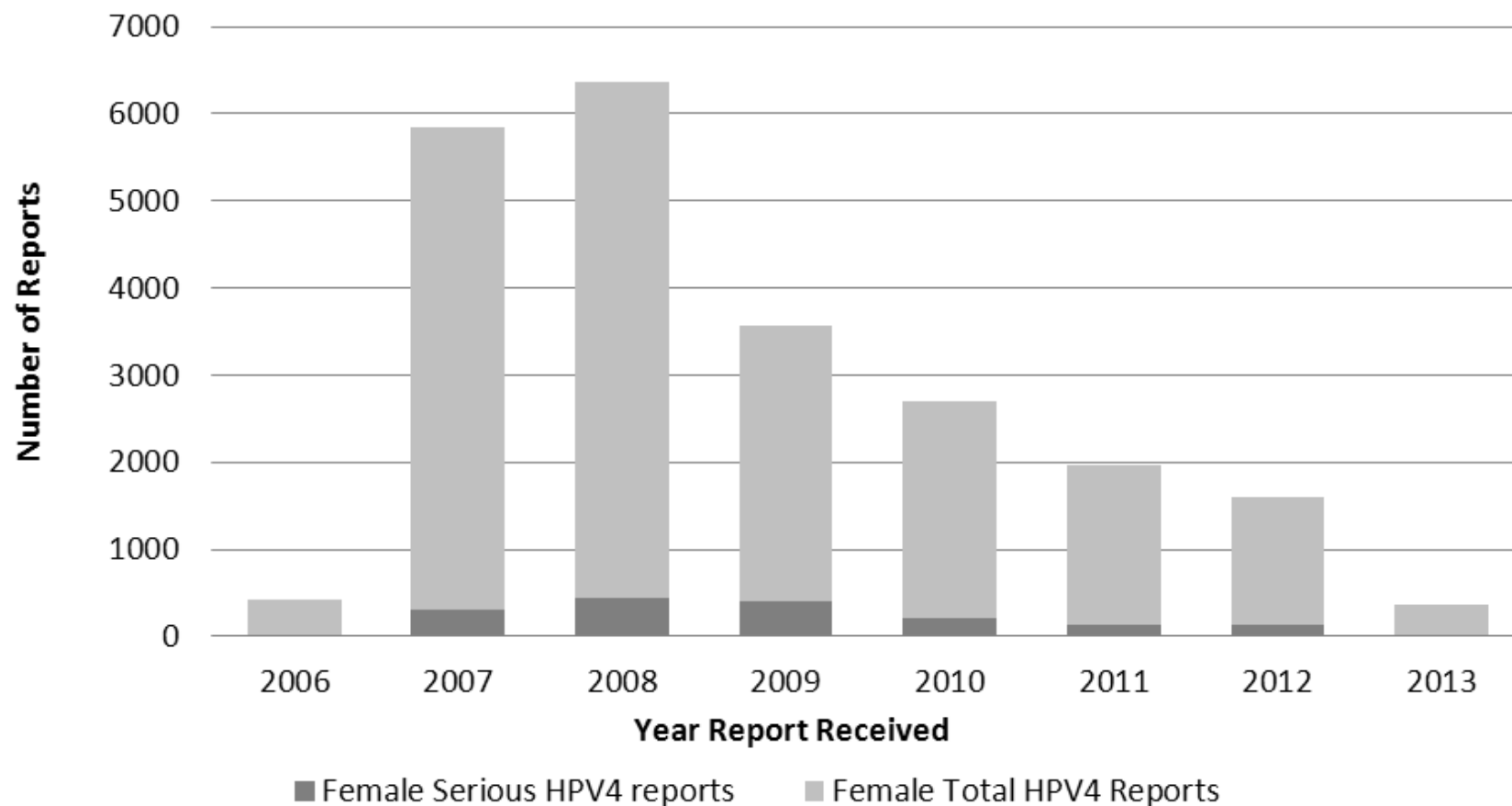
The Clinical Immunization Safety Assessment (CISA)

- Collaboration between CDC and several medical research centers in the United States to conduct research to understand how adverse events might be caused by vaccines

HPV Vaccine Safety Monitoring: VAERS

- **No new safety concerns have been identified in post-licensure vaccine safety surveillance among male or female recipients of HPV4 vaccine**
 - Among the 7.9% of reports coded as “serious”, most frequently cited are headache, nausea, vomiting, fatigue, dizziness, syncope, generalized weakness
- **Syncope continues to be a frequently reported adverse event following immunization among adolescents**
 - Adherence to a 15-minute observation period after vaccination is encouraged

Trends in Total and Serious Female HPV4 Vaccine Reports to VAERS by Year, June 2006 – March 2013 (N=21,194)



Institute of Medicine Report

Adverse Effects of Vaccines: Evidence and Causality

- ➡ IOM reviewed possible associations between adverse health events and eight vaccines
 - ➡ Evidence “favors acceptance” of a causal relationship between HPV vaccine and anaphylaxis (yeast and latex components)
 - ➡ Evidence “convincingly supports” a causal relationship between the injection of a vaccine and syncope
- ➡ Inadequate evidence was found for causal relationships between HPV vaccination and 12 other specific health events studied



HPV VACCINE IMPACT

HPV Vaccine Impact: HPV Prevalence Studies

➡ NHANES Study

- ➡ National Health and Nutrition Examination Survey (NHANES) data used to compare HPV prevalence before the start of the HPV vaccination program with prevalence from the first four years after vaccine introduction
- ➡ In **14-19 year olds**, vaccine-type HPV prevalence **decreased 56 percent**, from 11.5 percent in 2003-2006 to 5.1 percent in 2007-2010
- ➡ Other age groups did not show a statistically significant difference over time
- ➡ The research showed that vaccine effectiveness for prevention of infection was an estimated **82 percent**

HPV Vaccine Impact:

HPV Prevalence Studies, continued

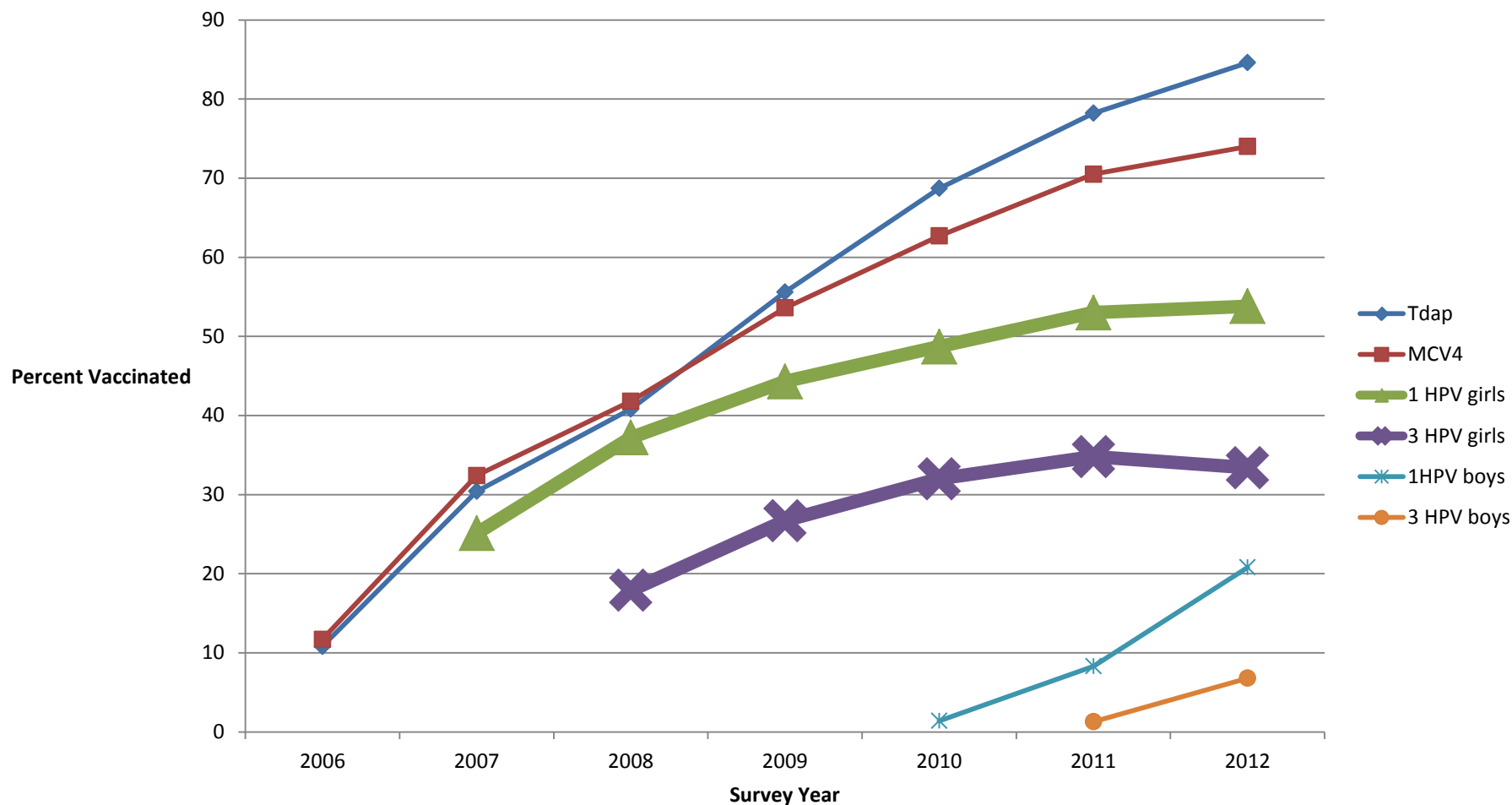
➡ Clinic-Based Studies

- ➡ Significant decrease from 24.0% to 5.3% in HPV vaccine type prevalence in at-risk sexually active females 14-17 years of age attending 3 urban primary care clinics from 1999-2005, compared to a similar group of women who attended the same 3 clinics in 2010
- ➡ Significant declines in vaccine type HPV prevalence in both vaccinated and unvaccinated women aged 13-26 years who attended primary care clinics from 2009-2010 compared to those from the pre-vaccine period (2006-2007)



HPV VACCINE COVERAGE

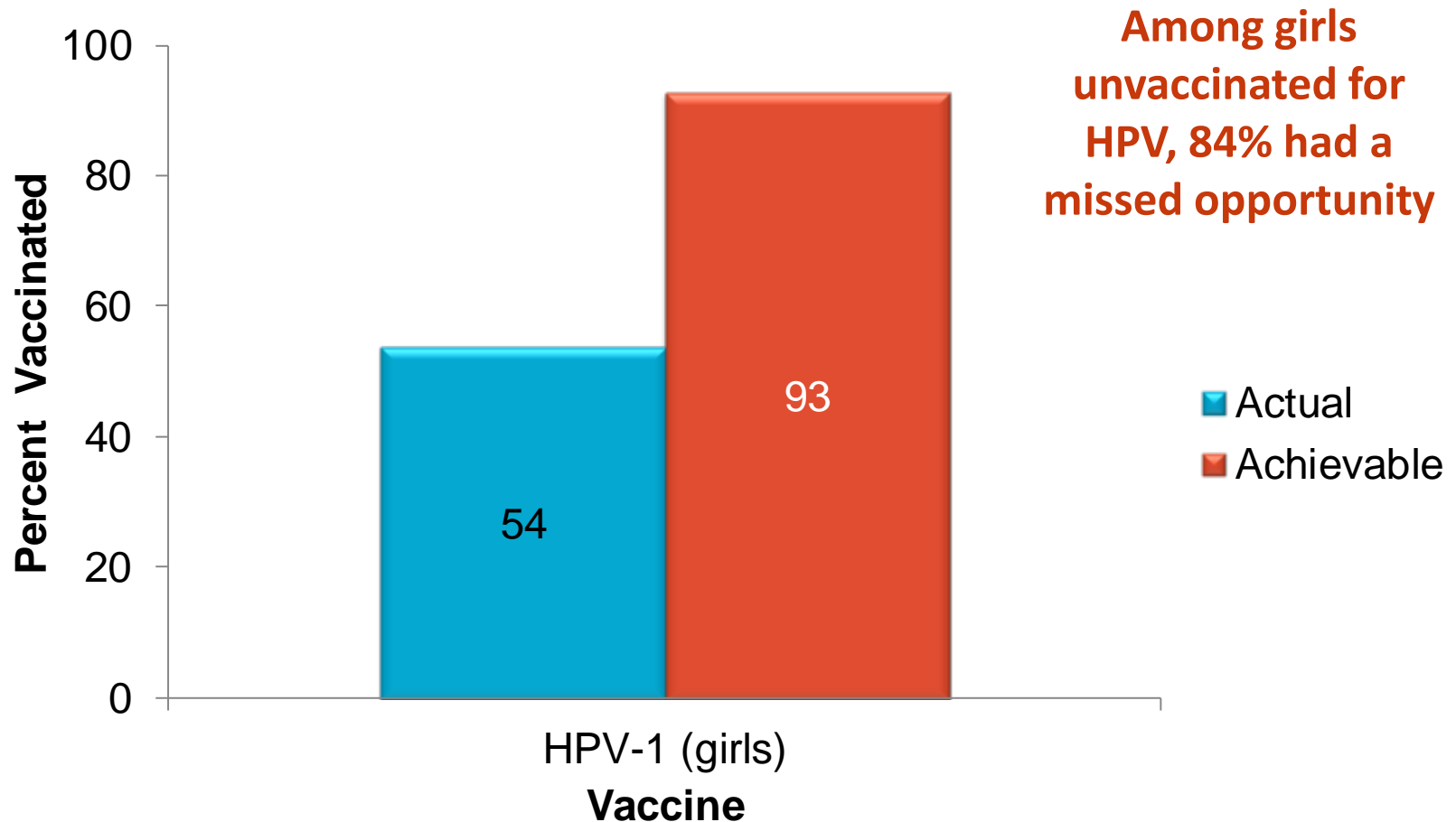
National Estimated Vaccination Coverage Levels among Adolescents 13-17 Years, National Immunization Survey-Teen, 2006-2012



Iowa

- National Immunization Survey - Iowa
 - Females, 3 doses: **35.6%** (33.4% National)
 - 1 dose: 57.5% (53.8% National)
 - Males, 1 dose: 19.4% (National 20.8%)
 - 3 dose data not available
- Iowa Immunization Program Annual Report, 2012
 - Females, 3 doses: 24%
 - Based on IRIS

Actual and Achievable Vaccination Coverage if Missed Opportunities Were Eliminated: Adolescents 13-17 Years, NIS-Teen 2012



Missed opportunity: Healthcare encounter when some, but not all ACIP-recommended vaccines are given.

HPV-1: Receipt of at least one dose of HPV.

Stokley S, Curtis R, Jeyarajah J. Human Papillomavirus Vaccination Coverage Among Adolescent Girls, 2007-2012, and Postlicensure Vaccine Safety Monitoring, 2006-2013 - United States. MMWR. 62(29);591-595.

Why We Need to Do Better in HPV Vaccination of 12 year olds

- ▶ Currently 26 million girls <13 yo in the US; If none of these girls are vaccinated then:
 - ▶ 168,400 will develop cervical cancer and
 - ▶ 54,100 will die from it
- ▶ Vaccinating 30% would prevent 45,500 of these cases and 14,600 deaths
- ▶ Vaccinating 80% would prevent 98,800 cases and 31,700 deaths

For each year we stay at 30% coverage instead of achieving 80%, 4,400 future cervical cancer cases and 1400 cervical cancer deaths will occur.

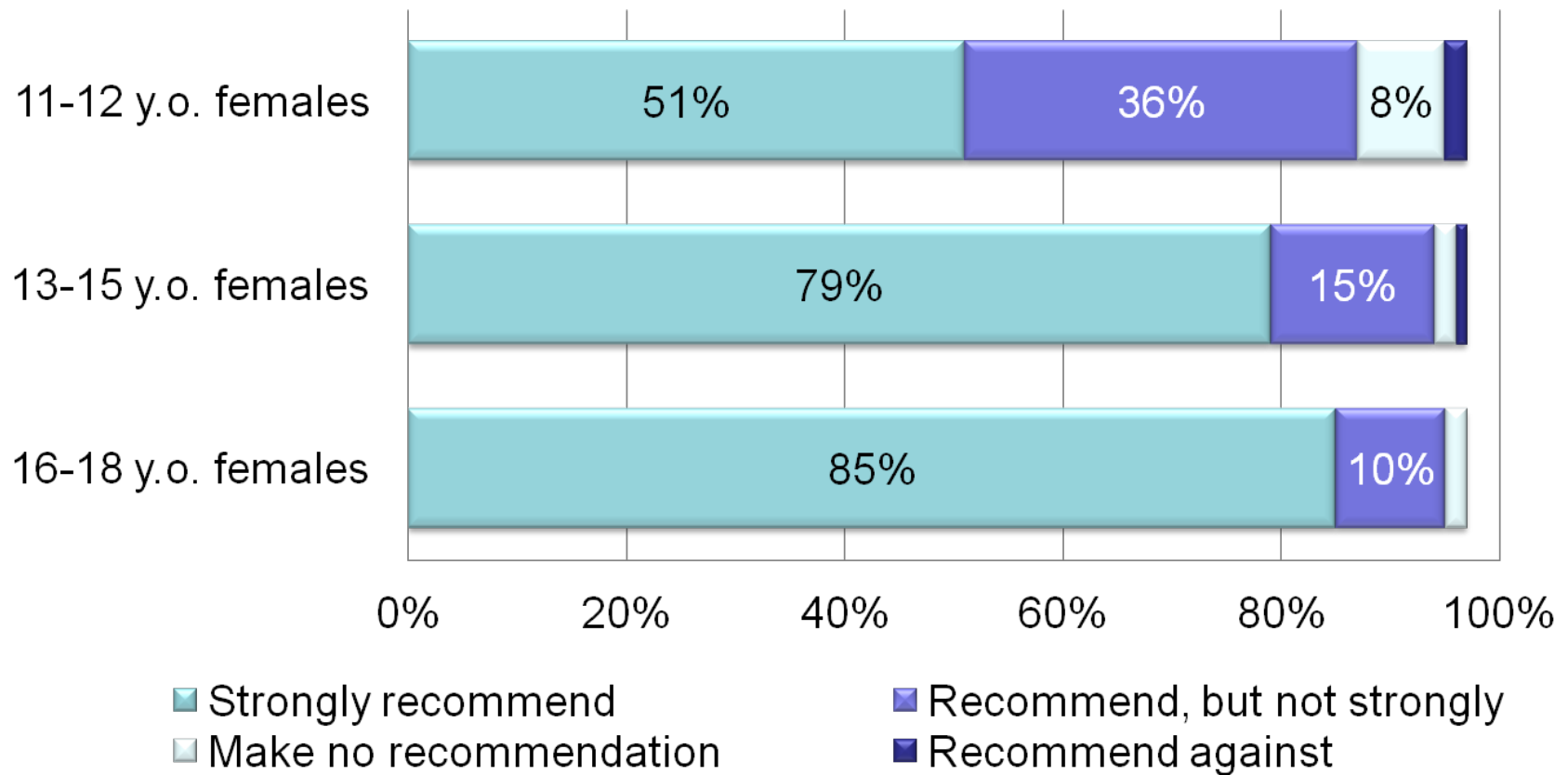


FRAMING THE CONVERSATION

What's in a recommendation?

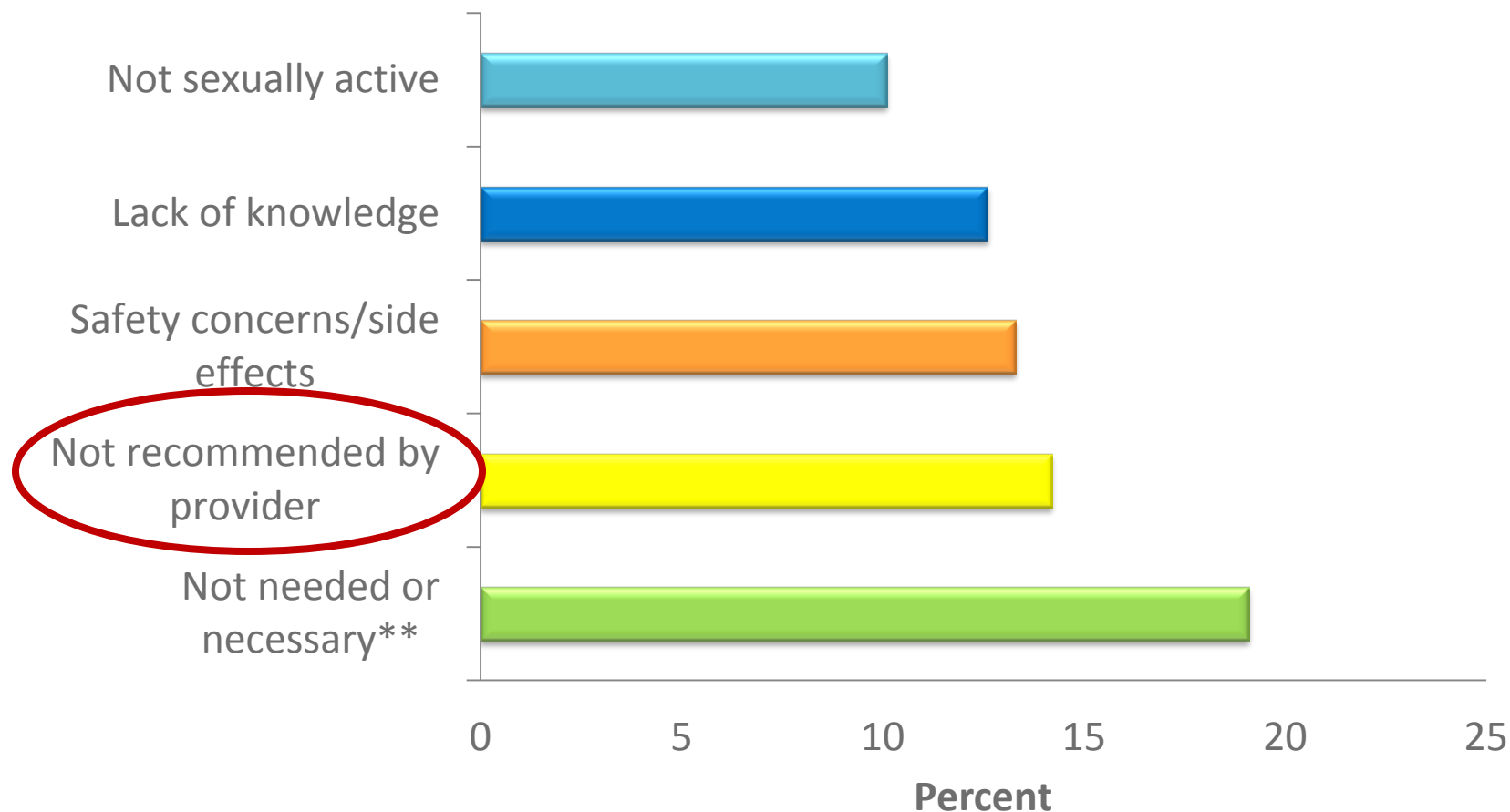
- ▶ **Studies consistently show that a strong recommendation from you is the single best predictor of vaccination**
- ▶ In focus groups and surveys, having a health care provider recommend or not recommend the vaccine was an important factor in parents'/patients' decision to vaccinate with the HPV vaccine
- ▶ Not receiving a recommendation for HPV vaccine was listed as a barrier

Strength of HPV Vaccine Recommendation for Female Patients, Pediatricians and Family Physicians (N=609)



Allison et al. <https://cdc.confex.com/cdc/nic2011/webprogram/Paper25181.html>

Top 5 reasons for not vaccinating daughter, among parents with no intention to vaccinate in the next 12 months, NIS-Teen 2012



* Not mutually exclusive.

** Did not know much about HPV or HPV vaccine.

Just another adolescent vaccine

- ▶ **Successful recommendations group all of the adolescent vaccines**
 - ▶ Recommend the HPV vaccine series the same way you recommend the other adolescent vaccines
 - ▶ Patients/families in focus groups who had not received a health care provider's recommendation stated that they questioned why they had not been told or *if the vaccine was truly necessary*
 - ▶ Many patients/parents responded that they trusted their health care provider and would get the vaccine as long as they received a recommendation from the health care provider

Try saying:

You need three shots today: HPV vaccine, meningococcal vaccine and Tdap vaccine.

You will get three shots today that will protect you from the cancers caused by HPV, as well as to prevent tetanus, diphtheria, pertussis and meningitis.

A case of vaccine hesitancy?

- ➡ **Patients may be interested in vaccinating, yet still have questions**
 - ➡ Many patients didn't have questions or concerns about HPV vaccine
 - ➡ A question from a patient does not mean they are refusing or delaying
 - ➡ Taking the time to listen to patients' questions helps you save time and give an effective response
 - ➡ CDC research shows these straightforward messages work with patients when discussing HPV vaccine—and are easy for you to deliver

An anti-cancer vaccine

- ▶ The “HPV vaccine is cancer prevention” message resonates strongly with patients/parents
 - ▶ In focus groups and online panels, patients/parents wanted more information on the types of HPV cancers
 - ▶ In focus groups patients/parents stated they were influenced to vaccinate their child because HPV vaccine prevents cancer, they had a family history of cervical cancers, and/or because they had a personal experience with cervical cancer

Try saying:

HPV vaccine is very important because it prevents cancer.

I want you to be protected from cancer.

That's why I'm recommending that you receive the first dose of the HPV vaccine series today.

Tell me, how bad is it?

- ➡ Disease prevalence is not understood, and patients/parents are unclear about what the vaccine actually protects against
 - ➡ Patients/parents in focus groups knew HPV vaccine can prevent cervical cancers, however they lacked knowledge about indications for HPV vaccine other than cervical cancer for girls, all HPV vaccine indications for boys, and the recommended ages to receive HPV vaccine

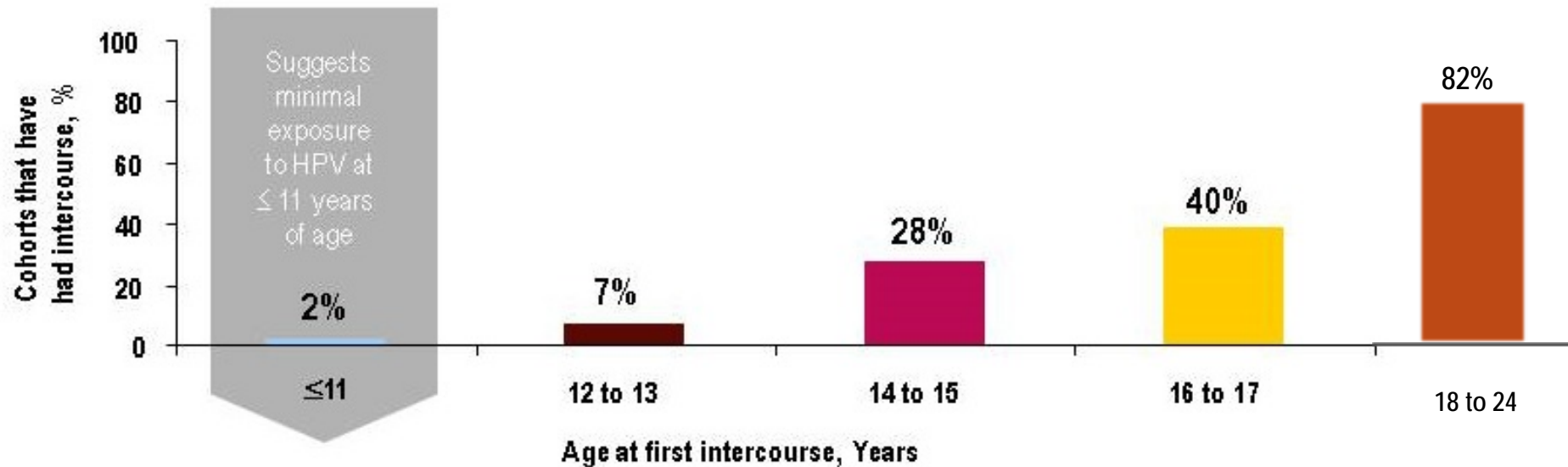
Try saying:

Persistent HPV infection can cause cancers of the cervix, vagina, and vulva in women, cancer of the penis in men, and cancers of the anus and the mouth or throat in both women and men.

There are about 26,000 of these cancers each year—and most could be prevented with HPV vaccine.

There are also many more precancerous conditions requiring treatment that can have lasting effects.

Rationale for vaccinating early: Protection prior to exposure to HPV



Adapted from Henry J. Kaiser Family Foundation

Try saying:

We're vaccinating today so you will have the best protection possible long before the start of any kind of sexual activity.

We vaccinate people well before they are exposed to an infection, as is the case with measles and the other routinely recommended childhood vaccines. Similarly, we want to vaccinate children long before they begin any type of sexual activity and are exposed to HPV.

Also HPV vaccine produces a better immune response in preteens than it does in older teens and young women.

A green light for sexual activity?

- **Parents may be concerned that vaccinating may be perceived by the child as permission to have sex**
 - In focus groups, some parents expressed concern that in getting HPV vaccine for their child, they would be giving their child permission to have sex
 - This was one of the top four reasons respondents gave when asked why they would not vaccinate their daughter
 - A few parents expressed that while they wanted their child to “wait to have sex” they understood that might not be the case

Receipt of HPV vaccine does not increase sexual activity or decrease age of sexual debut

- Kaiser Permanente Center for Health Research
- 1,398 girls who were 11 or 12 in 2006, 30% of whom were vaccinated, followed through 2010
- **No difference in markers of sexual activity**, including
 - Pregnancies
 - Counseling on contraceptives
 - Testing for, or diagnoses of, sexually transmitted infections

Try saying:

Multiple research studies have shown that getting the HPV vaccine does not make kids more likely to be sexually active.

These studies have also shown that getting the HPV vaccine does not make kids more likely to start having sex a younger age.

Would you give it to your child?

- ▶ **Emphasizing your personal belief in the importance of HPV vaccine helps parents feel secure in their decision**
 - ▶ Some respondents in focus groups stated that they would feel more comfortable knowing that the health care provider had vaccinated their own child or was planning to (if the child was <11)
 - ▶ Respondents in an online survey stated that knowing that oncologists supported the recommendation made them more likely to get their child vaccinated

Try saying:

I strongly believe in the importance of this cancer-preventing vaccine.

I have given HPV vaccine to my son/daughter (or grandchild/niece/nephew/friend's children).

Experts, such as the American Academy of Pediatrics, cancer doctors, and the CDC, also agree that getting the HPV vaccine is very important for your child.

Scared of side effects

- ➡ Understanding that the side effects are minor and emphasizing the extensive research that vaccines must undergo can help parents feel reassured
 - ➡ Moms in focus groups stated concerns about both short term and long term vaccine safety as a reason that they would not vaccinate their child
 - ➡ Respondents were not aware that HPV vaccine was tested in adolescents and adults and were concerned that their child's fertility could be affected by the vaccine

Try saying:

HPV vaccine has been very carefully studied by scientific experts and it's safety is continually monitored.

This is not a new vaccine and for years HPV vaccine has been shown to be very effective and very safe. HPV vaccine has a similar safety profile to the meningococcal and Tdap vaccines.

Like other shots, side effects can happen, but most are mild, primarily pain or redness in the arm. This should go away quickly, and HPV vaccine has not been associated with any long-term side effects.

Try saying:

Since 2006, about 57 million doses of HPV vaccine have been distributed in the U.S., and in the years of HPV vaccine safety studies and monitoring, no serious safety concerns have been identified.

There is no data to suggest that getting HPV vaccine will have an effect on future fertility. However, persistent HPV infection can cause cervical cancer and the treatment of cervical cancer can leave women unable to have children.

Even treatment for cervical pre-cancer can put a woman at risk for problems with her cervix during pregnancy which could cause preterm delivery or problems.

When do we come back?

- ➡ Many parents do not know that the full vaccine series requires 3 shots
- ➡ Your reminder will help them to complete the series
 - ➡ In focus groups, most respondents did not know the dosing schedule for HPV vaccine

How Can We Help?

1. Give a **STRONG** recommendation
 - Ask yourself, how often do you get a chance to prevent cancer?
2. Start conversation early and focus on **cancer prevention**
 - Vaccination given well before sexual experimentation begins
 - Better antibody response in preteens
3. Offer a **personal story**
 - Own children/Grandchildren/Close friends' children
 - HPV-related cancer case
4. Welcome **questions** from families, especially about safety
 - Remind parents that the HPV vaccine is safe and not associated with increased sexual activity

Summary

Almost everyone gets HPV and HPV can cause a variety of cancers in women and men

HPV vaccine is for cancer prevention

Provide a **strong recommendation for HPV vaccine** when patients are 11 or 12 years old

Listen carefully to and **welcome patient and family questions** especially about safety